

March 29, 2002

Courtney M. Price
Vice President
American Chemistry Council
1300 Wilson Blvd.
Arlington, VA 22209

Dear Dr. Price:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries for the Monocyclic Aromatic Amines category posted on the ChemRTK HPV Challenge Program Web site on October 5, 2001. I commend the MAANA Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

As outlined in the enclosed comments, the submitted robust summaries are not suitable as test plan support or as public information documents. Our ability to evaluate the test plan is contingent upon the submission within the next 90 days of substantially improved robust summaries that reflect the pertinent EPA guidance available for the HPV Challenge Program. EPA will post this letter and the attached Comments on the Chemical RTK Web site within the next few days.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: Anne LeHuray, ACC
W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Monocyclic Aromatic Amines

The sponsor, The Monocyclic Aromatic Amines and Nitroaromatics Panel of the American Chemistry Council, submitted a test plan and robust summaries to EPA for the Monocyclic Aromatic Amines category dated November 21, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 11, 2002. The category consists of four members: N,N-diethylaniline (CAS No. 91667), N,N-dimethyl-p-toluidine (CAS No. 99978), N-ethyl-m-toluidine (CAS No. 102272), and N-ethylaniline (CAS No. 103695).

SUMMARY OF EPA COMMENTS

EPA was unable to review the submission because of deficiencies in the data summaries (see comments below).

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

EPA COMMENTS ON THE MONOCYCLIC AROMATIC AMINES CATEGORY CHALLENGE SUBMISSION

The test plan comprises approximately five pages of text followed by over 500 pages of IUCLID data sets.

Some individual summaries are partly in German and partly in English. Others have both German and English versions, which sometimes do not match exactly. For example, in an N,N-dimethylaniline (121-69-7) four-month rat inhalation study, summarized in German on page 59/126, rats are exposed to concentrations of "0,011; 0,001 mg/l" five hours per day, six days per week. The same study was summarized in English on page 61/126, but the rats were exposed to "0.001 or 0.0107 mg/l". In addition to reporting slightly different exposure concentrations, the summaries differ in other details including the use of a control group and the description of the method. For the same chemical, on pages 60 and 61/126 another study is summarized in which three dose levels are reported in the German summary but only two in the English summary. For the analog aniline (CAS No. 62533), detailed descriptions of acute toxicity studies are all in German, and there may be other similar examples.

Extra work by reviewers is necessary to confirm identity of the German and English summaries even in cases where they appear identical, and in other cases to identify seemingly conflicting information, resolve the conflicts and form conclusions. **Such efforts are the responsibility of the submitter.**

The submitter needs to remove duplicate material and, because of the sparseness typical of many IUCLID summaries, ensure that they include all relevant material from the selected studies. Materials submitted under the HPV Challenge Program should be in English to facilitate review and ensure the widest possible access to this information through the ChemRTK Web site.

Followup Activity

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.